



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,912	11/19/2001	Avi Penner	262/229	1805
23639	7590	04/21/2004	EXAMINER	
BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO, SUITE 1800 SAN FRANCISCO, CA 94111-4067			LAYNO, CARL HERNANDZ	
			ART UNIT	PAPER NUMBER
			3762	10

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,912

Applicant(s)

PENNER ET AL.

Examiner

Carl H. Layno
4/14/04

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-14 is/are allowed.
- 6) ☒ Claim(s) 15-24, 27, 28, 31-34 and 36-38 is/are rejected.
- 7) ☒ Claim(s) 25, 26, 29, 30 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4.8.9.</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority as a Continuation-In-Part (CIP) to U.S. Application 09/690,615, now U.S Patent No. 6,628,989, filed October 16, 2000.

Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449) which were received by the Office on May 15, 2003, October 20, 2003, and April 28, 2003. These documents have been made of record in the file as Paper Nos. 4, 8, and 9, respectively.

Drawings

3. Applicant's formal drawings were received by the Office on March 11, 2003 and have been made of record in the file as Paper No.7. These drawings have been approved by the Examiner.

Specification

4. The disclosure is objected to because of the following informalities:

-p.1, lines 4-6, the reference to U.S. Application Serial Number "09/690,015" is a typographical error. This should be renumbered as "09/690,615". The first paragraph should be further updated to reflect the fact that this application is now U.S. Patent 6,628,989.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis for the term “the energy source” (line 1) in this claim or any of its base claims. To overcome this rejection, the Examiner suggests changing the dependency of the claim to depend from claim 35 instead of from claim 34.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15-24, 27, 28, 31-34, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh et al ‘265 in view of Funke ‘859 (both Applicant’s cited prior art).

The Walsh et al ‘265 patent, cited by the applicant as prior art, describes a system (Fig.3) including a peripherally located patch **202**, mounted on the skin of a patient, in communication with an implanted medical device (IMD) **216**. These elements may communicate between each other using *acoustic* telemetry techniques (Abstract, lines 20-24).

The Funke '859 patent, also cited by the applicant, describes a system (Fig.4) for communicating between externally located devices **42,66** and implanted medical devices **10,58** by transmitting and receiving acoustic signals using piezoelectric crystal transducers **40,65,26,70**.

Lacking any criticality, to have specified the use of piezoelectric acoustic transducers for use in the externally located patch and IMD of the Walsh et al patent, instead of electrodes, for enabling acoustic communication would have been an obvious design choice to one of ordinary skill in the art in view of the teachings of Funke '859, which teaches that the use of such transducers in the communication between IMDs and externally located control devices is well known. In addition, the Walsh et al patent makes specific mention that the use of the telemetry system of Funke may be employed (col.14, line 52).

In regard to claims 15-18, the patch **202** (Fig.4) of the modified Walsh et al system comprises all of applicant's claimed features including an acoustic transducer **210**, a controller/processor **206**, a power source/energy storage device **214**, memory **208**, and adhesive (not shown) for securing the patch to the patient's skin (col.9, lines 40-43).

In regard to claims 19 and 20, a miniature connector is used as an interface to download physiologic data from the memory **208** of patch **202** to a physician's computer based system via output device **212** (col.15, lines 47-50).

In regard to claim 21, the patch **202** is constructed of a flexible substrate **204**.

In regard to claims 28 and 31-33, the external patch **202** of the modified Walsh et al patent transmits a "Transfer Signal" command to the IMD, which in response, uplinks

Art Unit: 3762

physiological data into the patch device's memory (col.10, lines 9-18). See Fig.4, blocks **236**, **238**, **240**, and **242**.

In regard to claim 34, the data in the memory **208** of patch **202** is downloaded into a physician's computer at a physician's office or healthcare clinic (col.10, lines 52-56; Fig.4, block **252**).

In regard to claim 37 and 38, the patch **202** is secured to the patient's body by using an adhesive (not shown) (col.9, lines 40-43).

Allowable Subject Matter

9. Claims 25, 26, 29, 30, and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claim 36 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Claims 1-14 are allowed.

12. The following is a statement of reasons for the indication of allowable subject matter:

Independent claim 1 recites details of a system for activating an implant within a patient's body by receiving acoustic commands using a "second acoustic transducer". The commands

Art Unit: 3762

received by this transducer activate an "on/off" switch, which couples the implant's electrical circuit to its energy storage device. Most of the references of the prior art (mainly pacemakers and implanted defibrillators) perform this task using a magnetically activated Reed relay switch. The Examiner could find no examples of acoustically activated switches in this context. As a result, the Examiner deems claim 1 and its depending claims to be allowable over the prior art.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

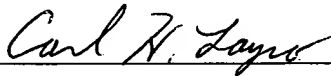
The Spillman, Jr. et al '488-B1 patent describes a system for interrogating an implanted device by using an external system using acoustic communications. The implanted device is also powered using acoustic energy. Unlike applicant's device, however, that of Spillman, Jr. et al does not have any means for securing its external device to the patient's skin.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed correspondence should be sent to the Office's new official FAX number (703) 872-9306.

Art Unit: 3762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

A handwritten signature in cursive script, reading "Carl N. Layno", is positioned above a horizontal line.

CARL LAYNO
PRIMARY EXAMINER

CHL
4/14/04